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DATE: August 31, 2007

TO: Examiner Kevin R. Kruer
Group Art Unit 1773

PHONE #: 571-272-1510
FAX #: 571-273-8300

Application No.: 10/790,338 OUR REF.: 2177.16US02
Applicant: LUTHRA et al.

FROM: Curtis B. Herbert, Ph.D., Esq.
PHONE #: 612-605-1038

Attached is the following for filing in the above-identified application.

1. Appeal Brief Transmittal; and
2. Appeal Brief with Appendixes.

Respectfully submitted,

Curtis B. Herbert, Ph.D.
Registration No. 45,443

CERTIFICATE OF FACSIMILE TRANSMISSION

I hereby certify that this paper is being transmitted by facsimile to the U.S. Patent and Trademark Office, Fax No. 571-273-8300 on the date shown below.

August 31, 2007
Date

Curtis B. Herbert, Ph.D., Esq.

Attorney Docket No. 2177.16US02

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APPEAL BRIEF TRANSMITTAL

In re the application of:

Luthra et al.

Application No.: 10/790,338 Confirmation No.: 9411

Filed: March 1, 2004 Examiner: Kruer, K.

Group Art Unit: 1773

For: POLYMERIC NETWORK SYSTEM FOR MEDICAL DEVICES AND METHODS OF USE

Mail Stop Appeal Brief-Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

Transmitted herewith is the Appeal Brief in the above-identified application, with respect to the Notice of Appeal filed on July 3, 2007.

[X] Applicant(s) is/are entitled to small entity status in accordance with 37 CFR 1.27.

[X] The Commissioner is hereby authorized to charge Deposit Account 50-3863 in the amount of [ ] $500.00 (large entity) [X] $250.00 (small entity) to cover the filing fee.

Respectfully submitted,

Curtis B. Herbert, Ph.D., Esq.
Registration No. 45,443

Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 50-3863.

CERTIFICATE OF FACSIMILE TRANSMISSION

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August 31, 2007
Date

Curtis B. Herbert, Ph.D., Esq.

PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of: Attorney Docket No.: 2177.16US02

Luthra et al. Confirmation No.: 9411

Application No.: 10/790,338 Examiner: Kruer, K.

Filed: March 1, 2004 Group Art Unit: 1773

For: POLYMERIC NETWORK SYSTEM FOR MEDICAL DEVICES AND METHODS OF USE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES

BRIEF FOR APPELLANT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re the application of:	Attorney Docket No.: 2177.16US02
Luthra et al.	Confirmation No.: 9411
Application No.: 10/790,338	Examiner: Kruer, K.
Filed: March 1, 2004	Group Art Unit: 1773

For: POLYMERIC NETWORK SYSTEM FOR MEDICAL DEVICES AND METHODS OF USE

BEFORE THE BOARD OF PATENT APPEALS AND INTERFERENCES
APPEAL BRIEF

Mail Stop Appeal Brief - Patents
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

INTRODUCTORY COMMENTS

This is an appeal of the final rejection of claims 54-104, 151-197, 199-206, and 209-215. A Final Rejection was mailed on May 3, 2007. A Notice of Appeal was filed July 3, 2007. This Appeal Brief is thus timely filed.

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Please grant any extension of time necessary for entry; charge any fee due to Deposit Account No. 50-3863.

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August 31, 2007
Date

Curtis B. Herbert, Ph.D., Esq.

REAL PARTY IN INTEREST

BioInteractions Ltd., a corporation organized and existing under the laws of England, and having its principal offices at University of Reading, Science & Technology Centre, Earley Gate, Whiteknights Road, Reading, Berkshire, England RG6 6BZ, has acquired the entire right, title and interest in and to the invention, the application, and any and all patents to be obtained therefore, as per the Assignment, recorded at Reel 014531, Frame 0595 from the inventors.

RELATED APPEALS AND INTERFERENCES

The assignee of the present application has no other applications presently on appeal. Since no other decided appeals are related in any relevant way to the present appeal, no earlier opinions are attached in the Related Appeals Appendix.

STATUS OF CLAIMS

Claims 54-104, 151-197, 199-206, and 209-215 are pending, and all of the pending claims stand rejected. Claims 1-53, 105-150, 198, 207 and 208 have been canceled. The pending claims are listed in the Appendix 1. All pending claims are being appealed.

STATUS OF AMENDMENTS

An Amendment After Final dated July 26. 2007 that amended claims 78-81, 83, 97-99, 164, 165, 183-185, 203-205 and 215 has been entered.

SUMMARY OF CLAIMED SUBJECT MATTER

The present invention is directed to polymeric coatings for medical devices or medical devices with polymeric coatings. The coating can contain a therapeutic agent. In particular, independent claims 54, 170, and 190 are directed to polymeric coatings for medical devices,

while independent claim 151 is directed to medical device with polymeric coatings. Appellant's specification describes the method of making a coating on a medical device with the delivery of a therapeutic agent. Application, page 17, line 15 to page 21, line 15. A "coating", as claimed, is explicitly defined at length in the paragraph bridging pages 17 and 18 of the Application and specifically excludes other polymeric constructs, e.g., sheaths, sleeves, membranes, and molded objects, that can be manufactured separately from a particular device. Coatings intimately contact the device for improved adherence and other properties helpful when the device is implanted. Application, page 2, lines 10-11. Further, coatings are more conveniently adapted for production processes than alternative processes such as molding a sheath or packing a sheath around the device. Application, page 2, lines 11-13.

This method is a significant inventive development. The present method is based in part on the recognition that a significant factor to control agent release is to achieve a particular average glass transition temperature (Tg) of the delivery matrix for agent-release applications in (or on) a patient's body. The copolymer design, however, goes far beyond merely choosing polymers to make a matrix for drug delivery having Tgs above or below a certain value. Application, page 12, lines 2-4. Without being bound to a particular theory, the claimed Tg differences between the various parts of the copolymer as claimed are believed to contribute to domain formation to achieve enhanced association of therapeutic agents with the domains. The domain-domain interactions may create small microvoids for therapeutic agents, or may form chemical associations with the therapeutic agents, which can be bonding associations or electrostatic interactions. Application, page 10, lines 9-14. Alternatively, it may be that the domains have irregular shapes and orientations that create microcavities. Then, larger domains could pack less efficiently into the layer so as to affect the quality of the microcavities. The microcavities may receive the therapeutic agent. Alternatively, it may be that the domains have irregular shapes and orientations that cause them to fold into three dimensional shapes in a melt or in a solution so as to create microcavities in the folded shape that receive the therapeutic

agent. For all of these reasons, it is useful to be able to make polymers, e.g., copolymers, from monomeric units having predetermined differences in Tgs. Application, page 11, lines 9-20.

More specifically, the independent claims 54, 170, and 190 are directed to a coating for a medical device for delivery of a therapeutic agent, the coating comprising a layer having a composition associated with at least a portion of the device, wherein the composition comprises the therapeutic agent associated with copolymer free of internal crosslinks and comprise a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit, wherein the coating comprising a layer with a thickness between about 0.1 μm and about 1000 μm (claim 54, see Application page 27, line 22), or wherein the coating comprising the layer has a glass transition temperature between 26 and about 40 degrees Centigrade as measured by differential scanning calorimeter (claim 170, see Application page 12, lines 15-19), or wherein the coating is included with a device that is selected from the group consisting of an implantable device, a device used topically on a patient, a device that contacts a living tissue, a catheter; a guide-wires, an embolizing coil, an implantable lead, an expandable balloon, a vascular graft, a heart valve, an implantable cardiovascular defibrillator, a pacemaker, a surgical patch, a wound closure, a microsphere, a biosensors, an implantable sensor, an ex-vivo sensor, an ocular implant, a contact lens, and a tissue engineering scaffold (claim 190, see Application page 26, line 20 to page 27, line 12).

Independent claim 151 is directed to an expandable medical device associated with a material composition for delivery of a therapeutic agent, comprising: an expandable portion of an expandable stent coated with a composition comprising the therapeutic agent associated with copolymer free of internal crosslinks and comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30

degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit (see Application, page 29, lines 10-12).

GROUNDS OF REJECTION TO BE REVIEWED ON APPEAL

1. The rejection of claims 54-104, 151-197, 199-206, and 209-215 as unpatentable under 35 U.S.C. § 112, first paragraph, as being failing to comply with the written description requirement.

2. The rejection of claims 167, 170-189, and 206 as unpatentable under 35 U.S.C. § 112, first paragraph, as being failing to comply with the written description requirement.

3. The rejection of claims 54-104, 151-197, 199-206, and 209-215 as unpatentable under 35 U.S.C. § 112, second paragraph, as being indefinite.

ARGUMENT

GROUPING OF CLAIMS

The following argument is organized around the following grouping of claims.

Group 1. Claims 54-104, 151-166, 168, 169, 190-197, 199-205, and 209-215 fall within a first claim group directed to a coating for a medical device for delivery of a therapeutic agent, wherein the coating comprising a layer with a thickness between about 0.1 μm and about 1000 μm or wherein the device is selected from a Markush Group of devices, or to an expandable medical device associated with a material composition for delivery of a therapeutic agent.

Group 2. Claims 167 and 206 fall within a second claim group directed to dependent claims of Group 1 having the limitation that the coating comprising the layer has a glass transition temperature between 26 and about 40 degrees Centigrade.

Group 3. Claims 170-189 fall within a third claim group directed to a coating for a medical device for delivery of a therapeutic agent wherein the coating comprising the layer has a glass transition temperature between 26 and about 40 degrees Centigrade.

LEGAL AUTHORITY

The Court of Appeals for the Federal Circuit has exclusive appellate jurisdiction for cases arising under the patent law under 28 U.S.C. § 1295 (a)(1). Federal Circuit patent law is subject to review by the U.S. Supreme Court, and the Supreme Court occasionally rules on patent cases that provide ultimate authority for interpreting the patent statutes. The Federal Circuit has adopted as binding precedent all holding of its predecessor courts, the U.S. Court of Claims and the U.S. Court of Customs and Patent Appeals. South Corp. v. U.S., 215 USPQ 657 (Fed. Cir. 1982). Therefore, unless they have been overruled *en banc* or by the Supreme Court, CCPA cases are binding precedent for the present appeal.

A. WRITTEN DESCRIPTION REQUIREMENT

Under 35 U.S.C. § 112, first paragraph, the "specification shall contain a written description of the invention,...." It has long been held that the written description requirement is separate from other patentability requirements. In re DiLeone, 168 USPQ 592, 593 (CCPA 1971)("[I]t is possible for a specification to enable the practice of an invention as broadly as claimed, and still not describe that invention."). It has also long been held that the specification does not need to use the exact language of the claim for the written description requirement to be satisfied. In re Smith, 178 USPQ 620, 624 (CCPA 1973)("This court has held that claimed

subject matter need not be described *in haec verba* in the specification in order for that specification to satisfy the description requirement, although where there is exact correspondence between the claim language and original disclosure, the description requirement would normally be satisfied."). "A fairly uniform standard for determining compliance with the 'written description' requirement has been maintained throughout [the period from the Federal Circuit's inception]: 'Although [the applicant] does not have to describe exactly the subject matter claimed, . . . the description must clearly allow persons of ordinary skill in the art to recognize that [he or she] invented what is claimed.'" Vas-Cath, Inc. v. Muhurkar, 19 USPQ2d 1111, 1116 (Fed. Cir. 1991)(quoting from In re Gosteli, 10, USPQ2d 1614, 1618 (Fed. Cir. 1989)).

Within this well settled framework, written description requirements relating to a range limitation in a claim have also been settled for many years. In 1976, for example, the Court of Customs and Patent Appeals held that a disclosure of a range of 25% to 60% solids content, which was supported by two examples that fell within that range, was sufficient support for a claim to a range of 35% to 60%. In re Wertheim, 191 USPQ 90, 98 (C.C.P.A., 1976). The court further held that: "Inventions are constantly made which turn out to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. . . . **To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed.**" Id. at 97 (emphasis added). "The burden of showing that the claimed invention is not described in the specification rests on the PTO in the first instance, and it is up to the PTO to give reasons why a description not in ipsis verbis is insufficient." Id.

The Court of Customs and Patent Appeals also articulated this principle in In re Eickmeyer (202 USPQ 655 (C.C.P.A. 1979)) when it stated that an applicant "need not claim all he is entitled to claim and need have support only for what he does claim. **We are not persuaded that there is any requirement for [an applicant] to demonstrate the criticality of**

a lower limit to meet a description requirement." Id. at 663 (emphasis added). On the facts of this case, replicate tests at 56°C and 80°C along with knowledge in the art that comparable process could be operated above 80°C were found to support a claim to the process at an elevated temperature of at least about 56°C. Id.

Similarly, in an interference context, a disclosure in a grandparent application of a nickel concentration from 45% to 55% was found to provide written description for "about 45% to about 55%" but not for the range of 50% to 60% that extended significantly beyond the limit in the grandparent application. Eiselstein v. Frank, 34 USPQ2d 1467, 1471 (Fed. Cir. 1995). Similarly, the disclosure in a specification of 4-12 turns per inch with 8 being preferred was found to support a range of 8-12 turns per inch in the issued claim for a yarn. Kolmes v. World Fibers Corp., 41 USPQ2d 1829, 1832 (Fed. Cir. 1997). As described in a recent Federal Circuit case, the explicit description should be gleaned for what it describes to a person of ordinary skill in the art. Enzo Biochem Inc. v. Gen-Probe Inc., 63 USPQ2d 1609, 1615 (Fed. Cir. 2002), reversing upon rehearing an earlier decision at 62 USPQ2d 1289 (Fed. Cir. 2002).

B. INDEFINITENESS

The patent statute at 35 U.S.C. § 112, second paragraph, requires that the "specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention." "Whether a claim is invalid for indefiniteness requires a determination whether those skilled in the art would understand what is claimed when the claim is read in light of the specification." Morton International Inc. v. Cardinal Chemical Co., 28 USPQ2d 1190, 1194 (Fed. Cir. 1993). "Definiteness problems often arise when words of degree are used in a claim. That some claim language may not be precise, however, does not automatically render a claim invalid." Seattle Box CO. v. Indus. Crating & Packing, Inc., 731 F.2d 818m, 826 (Fed. Cir. 1984).

ANALYSIS

I. Rejection Under 35 U.S.C. § 112 first paragraph

The Examiner rejected claims 54-104, 151-197, 199-206, and 209-215 under 35 U.S.C. §112, first paragraph as failing to comply with the written description requirement. The Examiner asserts on page 2 of the final Office Action that "The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, has possession of the claimed invention.

A. The rejection of the claims of Groups 1, 2 and 3 for lack of written description for the term "free of covalent crosslinks" fails because this limitation is explicitly supported in the specification and because the Office Action's *prima facie* case of rejection used the wrong legal standard.

With respect to Groups 1 and 2 (claims 54-104, 151-169, 190-197, 199-206, and 209-215), the Examiner stated on page 2 of the Office Action that there is no explicit support for the limitation "free of covalent bonds" and that, furthermore, there is no evidence to show that such a teaching is inherent. The Office Action is understood as not rejecting the Group 3 claims on this basis because the disputed term "free of covalent crosslinks" is not present in the independent claims of Group 3. The Office Action refers to the term "free of covalent bonds" but this term is absent from the claims; it is understood that the Office Action was actually referring to the claimed "free of covalent crosslinks" term.

The Office Action states that the limitation "free of covalent crosslinks" is understood not to be inherent to the inventive examples in the specification for the reasons stated in the previous action. Specifically, the previous office action dated January 7, 2007 stated that "The hydroxyl functional methacrylates utilized in examples 1-8 are capable of forming crosslinks with other functional groups in the polymer, with additives such as the therapeutic agent, or with an

adjacent layer. Furthermore, the polymers of examples 1-8 are not commensurate in scope with the claims because said polymers are not applied as coatings." The Appellants respectfully disagree.

The limitation "free of covalent crosslinks" (independent claims 54, 151, and 190) is supported in the specification. A copolymer in a coating would normally be considered to be free of covalent crosslinks unless it is taught as being crosslinked: this consideration follows from the fact that copolymers formed into a coating do not form covalent crosslinks with each other unless crosslinking molecules or crosslinking chemical groups are present. In this case, the Applicant has described copolymers that are free of covalent crosslinks, as explained below. The Applicant has provided actual working Examples of the claimed copolymers and can not be expected to list features that are obviously absent from them.

The Applicant's Examples 1-5, among others, describe copolymers that are free of covalent crosslinks, so those skilled in the art necessarily appreciate that the Applicant possessed copolymers that are free of covalent crosslinks. Monomers with a single double bound (e.g., methacrylate or acrylate) will polymerize to form a polymer that is free of crosslinks: this is a foundational principle of polymer science that is used to make linear polymers. A single double bond can react with another single double bond to make a linear chain. Molecules with two double bounds (e.g., di-methacrylate or di-acrylate) can be used to make crosslinked polymeric materials because each of the double bonds can help to form part of a linear polymer, so that various chains are interconnected as the polymer grows.

Specifically, for instance, Example 1 describes a 2-hydroxyethyl methacrylate-co-butyl acrylate-co-butyl methacrylate copolymer. This is a linear polymer made with three different types of monomers (an acrylate and two types of methacrylates). It is necessarily free of covalent crosslinks because all of the monomers have just one double bond. Indeed, the copolymer must be fee of crosslinks and an artisan familiar with these arts will immediately understand that it must be free of crosslinks since this is an inherent property and also is implicitly understood. Similarly, other Examples describe copolymers that are necessarily free

of covalent crosslinks: Example 2 describes a 2-Hydroxyethyl methacrylate-co-butyl acrylate-co-butyl methacrylate copolymer, Example 3 describes a Poly(hydroxyethyl methacrylate-co-butylacrylate copolymer, Example 4 describes a Poly(hydroxyethyl methacrylate-co-lauryl methacrylate copolymer, and Example 5 describes a Poly(polyethylene glycol mono methacrylate-co-butyl acrylate-co-butyl methacrylate copolymer.

The Office Action of January 7, 2007 states that the hydroxyls of the Examples 1-8 are known to be capable of crosslinks. This statement is irrelevant to the rejection because what is claimed is "free of covalent crosslinks". Pointing to the **potential** of the copolymer to make a covalent crosslink does not contradict the claimed "free of covalent crosslinks". In fact, the Office Action is supporting Applicant's position by pointing out that the copolymers are not **actually** covalently crosslinked.

The Office Action of January 7, 2007 states that the polymers of Examples 1-8 are not commensurate in scope with the claims because said polymers are not applied as coatings. Example 8, however, describes methods of applying polymers (e.g., copolymers) as taught in the Application onto medical devices with a spray technique that deposits a coating on the device so that a "coating" as claimed is made, see Application page 37, lines 11-17. Since a coating is taught, in Example 8, among other places in the Application, these concerns about Examples not showing coatings do not seem to be justified.

The remaining concern expressed in the rejection is that "free of covalent crosslinks" does not have inherent support. It is well established that claim limitations must be supported in the specification through express, implicit, or inherent disclosure (See MPEP 2163). The fundamental factual inquiry is: *whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed.* (See MPEP 2163.02). As already explained, there is more than adequate support for the claimed limitation. The Patent Office's suggestion that the claimed limitation must be inherently supported is not correct. Since a person of ordinary skill in the art can evaluate the

meaning of the claims, the Examiner has not established a *prima facie* case of failing to comply with the written description requirement of the claims. Appellants respectfully request withdrawal of the rejection of the claims as failing to comply with the written description requirement.

B. The rejection of the claims of Groups 2 and 3 for lack of written description for the term "26 degrees Centigrade" fails because (1) this limitation is explicitly supported in the specification and (2) the written description requirement is not an adequate basis to deny the Applicant the right to amend a range in light of the prior art.

Two reasons for overturning the Office Action are provided, with each reason being dispositive in favor of Applicant and supported by various arguments.

The Examiner rejected the claims of Groups 2 and 3 (claims 167, 170-189, and 206) as unpatentable under 35 U.S.C. § 112, first paragraph, as being failing to comply with the written description requirement. The Examiner asserts on page 3 of the final Office Action that "the original disclosure does not contain support for the endpoint "26 degree Centigrade."

Claims 167, 170-189, and 206 are directed to a copolymer or coating with a glass transition temperature between 26 and about 40 degrees Centigrade.

1. The claimed range of between 26 and about 40 degrees Centigrade is explicitly and implicitly supported in the Application.

The Application discloses that "In some embodiments, it is advantageous to choose a particular average Tg. For instance, polymeric implants loaded with a therapeutic agent can be made with polymers or copolymers having a Tg that is close to a physiological temperature" see page 12, lines 7-9. The Application also states that "Moreover, the combination of blocks may be made to have an average Tg that is comparable to a physiological temperature of a patient that receives an implant that has such a copolymer. Thus, a copolymer may, in addition to one or more of the other features already described, be made to with a composition of monomeric units that have an average Tg that approaches a physiological temperature of about 37°C", see

Application, page 5 line 21 to page 6 line 2. Firstly, it is submitted that the claimed temperature between 26 and about 40 degrees Centigrade is understood by ordinary artisans as approaching a physiological temperature or as being comparable to a physiological temperature in the claimed context. As discussed above, the Application further discloses the role of Tg with respect to release of a therapeutic agent, so this portion of the disclosure can reasonably be read with a wide scope, with something between about room temperature (26 Centigrade) and somewhat over physiological temperature being a reasonable range.

Secondly, the Application states that "Weigbted Tg averages for copolymers and polymers as set forth herein include from . . . about 0°C to about 40°C. Persons of ordinary skill in these arts, after reading this disclosure, will appreciate that all ranges and values within these explicitly stated ranges are contemplated", see Application at page 12, lines 15-19. This disclosure thus provides **explicit** support for all ranges and values from about 0°C to about 40°C, **including the claimed range** starting at 26 °C, such that 35 U.S.C. §112¶1 is explicitly satisfied.

2. The written description requirement is not an adequate basis to deny the Applicant the right to amend a range in light of the prior art; case law plainly states that the Applicant has the opportunity to make such amendments.

The Patent Office has taken the position that Applicant does not possess the claimed range because there is no literal support for the range. Respectfully, this position is a clear error and directly contradictory to established case law as explicitly stated in In re Wertheim, 541 F.2d 257, 191 U.S.P.Q. 90 (CCPA, 1976): "The PTO has done nothing more than to argue lack of literal support, which is not enough. If lack of literal support alone were enough to support a rejection under §112, then the statement of In re Lukach, supra, 442 F.2d at 969, 58 CCPA at 1235, 169 USPQ at 796, that 'the invention claimed does not have to be described in *ipsis verbis* in order to satisfy the description requirement of § 112,' is empty verbiage. The burden of showing that the claimed invention is not described in the specification rests on the PTO in the

first instance, and it is up to the PTO to give reasons why a description not in ipsis verbis is insufficient." In re Wertheim, 541 F.2d 257, 265.

In re Wertheim **directly addresses the present issue.** The applicant's specification described a broad range of 25% to 60% solids. To avoid the prior art, the applicant claimed between 35% and 60% solids. The Patent Office maintained a written description rejection on the grounds that the claimed range lacked literal support. The court held that this position was wrong. In re Wertheim, 541 F.2d 257, 265. The court explained that "Inventions are constantly made which turn out not to be patentable, and applicants frequently discover during the course of prosecution that only a part of what they invented and originally claimed is patentable. As we said in a different context in In re Saunders, 444 F.2d 599, 607, 58 CCPA 1316, 1327, 170 USPQ 213, 220 (1971): To rule otherwise would let form triumph over substance, substantially eliminating the right of an applicant to retreat to an otherwise patentable species merely because he erroneously thought he was first with the genus when he filed." In re Wertheim, 541 F.2d 257, 263.

The burden of proof lies with the Patent Office to establish a written description rejection. As stated at MPEP 2163.04, a description as filed is **presumed** to be adequate, unless or until **sufficient evidence or reasoning to the contrary** has been presented by the examiner to rebut the presumption. The Patent Office has the **initial burden of presenting by a preponderance of evidence** why a person skilled in the art would not recognize in an applicant's disclosure a description of the invention defined by the claims. MPEP 2163.02 states that "The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon 'reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter'". The claimed invention is explicitly described over the claimed range and there is no reason to believe that Applicant did not possess the claimed range.

The test for written description is *possession.* The Applicant clearly possessed 0-40 degrees C, as well as various intermediate points, so that there is no rational basis for seizing

upon 26 degrees or the range 26-40 as not being possessed. What is lacking is an explanation of how 26-40 degrees *is not* possessed despite the fact that 0-40 *is* possessed. The Office Action's case fails the legal requirement that the Patent Office must provide a basis for a written description rejection beyond a mere demand for *ipsis verbis* support.

Appellants respectfully request withdrawal of the rejection of the claims of Groups 2 and 3 (claims 167, 170-189, and 206) under 35 U.S.C. §112, first paragraph, as failing to comply with the written description requirement.

Rejection Under 35 U.S.C. § 112 second paragraph

The Examiner rejected claims 54-104, 151-197, 199-206, and 209-215 (Groups 1, 2, and 3) under 35 U.S.C. §112, second paragraph as being indefinite. The Examiner asserts on page 3 of the final Office Action that "It is unclear how the skilled artisan would go about distinguishing "covalent crosslinks" from ionic crosslinks since virtually every bond has some ionic and some covalent characteristics." This naked assertion is made without reference to any authority or form of evidence and fails to establish a prima facie case for the rejection. Moreover, even if the Patent Office's assertion were to be accepted, it would not mean that some degree of commonality would prevent artisans from distinguishing covalent bonds from ionic bonds in the context of the claims.

The correct standard for determining indefiniteness is whether those skilled in the art would understand what is claimed. Respectfully, it is well known that the terms "ionic" and "covalent" are commonly used to distinguish different types of bonds, such that artisans can readily distinguish covalent bonds from ionic bonds. There is a reason that these terms are commonly employed: these terms are commonly known and used in these arts as identifying different categories of bonds; in covalent bonding, the bond is formed from the sharing of electrons, while in ionic bonding, the bond is based on electrostatic forces between two oppositely-charged ions. One with ordinary skill in the art would understand the clear distinction

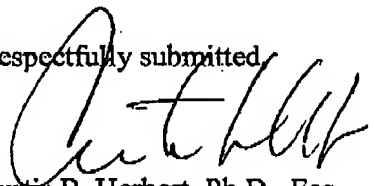
between covalent crosslinks from ionic crosslinks. The definitions for "ionic bond" and "covalent bond" are commonly available in textbooks and from various sources such as *The American Heritage Dictionary*. For instance, Answers.com provides a dictionary definition (from The American Heritage® Dictionary of the English Language, Fourth Edition Copyright © 2007, 2000 by Houghton Mifflin Company. Updated in 2007. Published by Houghton Mifflin): "covalent bond, *n.*, A chemical bond formed by the sharing of one or more electrons, especially pairs of electrons, between atoms", and "ionic bond, n., A chemical bond between two ions with opposite charges, characteristic of salts."

Since a person of ordinary skill in the art can evaluate the meaning of the claims, Appellants respectfully request withdrawal of the rejection of claims 54-104, 151-197, 199-206, and 209-215 under 35 U.S.C. §112, second paragraph as being indefinite.

CONCLUSIONS

Applicants believe that the Patent Office has failed to meet their burden of persuasion with respect to unpatentability of any of the claims on the present record. Thus, Applicants Respectfully request the Appeals Board to reverse of the rejections of claims 54-104, 151-197, 199-206, and 209-215.

Respectfully submitted,



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CLAIMS APPENDIX

PENDING CLAIMS

1.-53. (Cancelled)

54. (Previously Presented) A coating for a medical device for delivery of a therapeutic agent, the coating comprising a layer with a thickness between about 0.1 μm and about 1000 μm and having a composition associated with at least a portion of the device, wherein the composition comprises the therapeutic agent associated with copolymer free of covalent crosslinks that has a weight averaged molecular weight of at least about 2500, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit.

55. (Original) The coating of claim 54 wherein at least a portion of the first monomer units are organized into a plurality of blocks consisting essentially of repeats of the first monomer unit, and at least a portion of the second monomer units are organized into a plurality of blocks consisting essentially of repeats of the second monomer unit.

56. (Original) The coating of claim 55 wherein the copolymer further comprises regions of random copolymer bonding.

57. (Original) The coating of claim 54 wherein the copolymer comprises a third monomer unit and comprises at least three blocks, wherein each block consists essentially of repeats of one type of monomer unit.

58. (Original) The coating of claim 54 wherein the copolymer comprises acrylate blocks and methacrylate blocks.

59. (Original) The coating of claim 54 wherein the therapeutic agent associates with blocks within the copolymer.

60. (Original) The coating of claim 54, wherein the second monomer unit has a glass transition temperature that is at least about 50 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

61. (Original) The coating of claim 54, wherein the second monomer unit has a glass transition temperature that is at least about 70 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

62. (Original) The coating of claim 54 wherein the first monomer unit comprises an acrylate and the second monomer unit compromises a methacrylate.

63. (Original) The coating of claim 54 wherein the first monomer unit and the second monomer unit selected from a member of the group consisting of acrylic acid, acrlonitrile, allyamine, acrylates, methacrylates, methylmethacrylate, alkyl acrylates, alkyl methacrylate, butadiene, carbomethylsilane, (carbonate) urethane, acrylates of polydimethyl siloxanes, methacrylates of polydimethyl siloxanes, ethylene, ethylene glycol, propylene glycol, (ether)

urethane, urethane, vinyl chloride, vinyl alcohol, maleic anhydride, cellulose nitrate, carboxy methyl cellulose, dextran, dextran sulphate, propylene, esters, carbonates, ethers, butenes, maleic acid, fluoropolymer monomeric units, unsaturated polymer monomeric units, isoprene, melamine, sulphone, ureas, biological polymer monomeric units, protein, gelatin, collagen, elastin, butyl methacrylate, hydroxyethyl methacrylate, methacrylate acid, polyethylene glycol dimethacrylate, polypropylene glycol diglycidal ether, polyethylene glycol diglycidyl ether, isocyanatoethyl methacrylate, N-acryloxysuccinimide, glycidyl methacrylate, hexamethylene diisocyanate, acrolein, crotonaldehyde, glycerol monomethacrylate, heparin methacrylate, methacryloylethyl phosphorylcholine, polymethacrylatea, polyacrylate, polyester, polyether, polyethylene glycol, butyl acrylate, polyethylene glycol monomethacrylate, isobutyl methacrylate, cyclohexyl methacrylate, ethyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, methyl acrylate, hexadecyl methacrylate, octadecyl methacrylate, styrene, methyl styrene, vinyl sterate, vinyl toluene, and tert-butyl acrylate.

64. (Original) The coating of claim 54 wherein the copolymer further comprises a third monomer unit, wherein the third monomer unit forms a homopolymer with a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of a homopolymer formed by the first monomer unit.

65. (Original) The coating of claim 64 wherein the first monomer unit comprises an acrylate, the second monomer unit compromises a methacrylate, and the third monomer unit comprises a methacrylate.

66. (Original) The coating of claim 64 wherein the copolymer comprises a homopolymer of the first monomer unit covalently joined to a homopolymer of the second monomer unit.

67. (Original) The coating of claim 66 wherein a first polymer comprises a first monomer unit and a second polymer comprises at least one member of the group consisting of the first monomer unit, the second monomer unit, and both the first monomer unit and the second monomer unit.

68. (Original) The coating of claim 54 wherein the copolymer comprises at least two methacrylate monomer units.

69. (Original) The coating of claim 54 wherein the copolymer comprises a member of the group consisting of poly(hydroxyethyl methacrylate-co-butylacrylate-co-butylmethacrylate), poly(hydroxyethyl methacrylate-co-lauryl methacrylate), poly(polyethylene glycol monomethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(heparin methacrylate-co-hydroxyethylmethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(glycerol monomethacrylate-co-butyl acrylate-co-butyl methacrylate), poly(amino methacrylate hydrochloride-co-butyl acrylate-co-butyl methacrylate), poly(isocyanatoethyl methacrylate-co-butyl acrylate-co-butyl methacrylate) and poly (methoxy(polyethylene glycol) monomethacrylate-co-lauryl methacrylate-co-butyl methacrylate-co-ethylene glycol dimethacrylate).

70. (Original) The coating of claim 54 wherein the monomer units are polymerizable to form the copolymer after the monomer units have been associated with the medical device.

71. (Original) The coating of claim 54 wherein the medical device is a stent and the therapeutic agent is paclitaxel.

72. (Original) The coating of claim 54 wherein the copolymer is prepared and is subsequently associated with the therapeutic agent.

73. (Original) The coating of claim 54 wherein the copolymer is prepared from the monomer units from a melt of the monomers.

74. (Original) The coating of claim 54 wherein the first monomer unit and the second monomer unit are chosen so that the first monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the first monomer unit and the second monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the second monomer unit.

75. (Original) The coating of claim 54 further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

76. (Original) The coating of claim 75 wherein the first layer is at least partially disposed between the device and the second layer.

77. (Original) The coating of claim 75 wherein the second layer is at least partially disposed between the device and the first layer.

78. (Previously Presented) The coating of claim 75 wherein the second layer comprises a polymer that is covalently crosslinked to a polymer of the first layer.

79. (Previously Presented) The coating of claim 78 wherein the copolymer comprises reactive functional groups that are involved in forming covalent crosslinks with the second layer,

and wherein the reactive functional groups are chosen from the group consisting of hydroxyl, amine, carboxylic, aldehyde, ketone, thiol, allyl, acrylate, methacrylate, isocyanate, epoxide, azides, aziridines, acetals, ketals, alkynes, acyl halides, alky halides, hydroxy aldehydes and ketones, allenes, amides, bisamides, amino acids and esters, amino carbonyl compounds, mercaptans, amino mercaptans, anhydrides, azines, azo compounds, azoxy compounds, boranes, carbamates, carbodimides, carbonates, diazo compounds, isothionates, hydroxamic acid, hydroxy acids, hydroxy amines and amides, hydroxylamine, imines, lactams, nitriles, sulphonamides, sulphones, sulphonic acids, thiocyanates, and combinations thereof.

80. (Previously Presented) The coating of claim 78 wherein the second layer comprises a heparin macromer that comprises a second reactive functional group that is involved in forming the crosslinks with the first layer.

81. (Previously Presented) The coating of claim 78 wherein the polymer of the second layer comprises monomer units that comprise a heparin macromer.

82. (Previously Presented) The coating of claim 78 wherein the polymer of the second layer comprises a second functional group that forms at least one of the covalent crosslinks in response to exposure to light.

83. (Previously Presented) The coating of claim 82 wherein the second functional group comprises azide.

84. (Original) The coating of claim 75 wherein the first layer comprises the therapeutic agent and the second layer does not comprise the therapeutic agent.

85. (Original) The coating of claim 75 wherein the second layer reduces the rate of release of the therapeutic agent from the first layer.

86. (Original) The coating of claim 75 wherein the second layer is in contact with the medical device and comprises a polymer having at least one reactable monomer.

87. (Original) The coating of claim 86 wherein the at least one reactable monomer is a member of the group consisting of acrylates and methylmethacrylates.

88. (Original) The coating of claim 87 wherein the polymer in the second layer is a second copolymer that comprises monomer units of at least one member of the group consisting of vinyl chloride, vinyl acetate, and co-vinyl alcohol.

89. (Original) The coating of claim 87 wherein the polymer in the second layer comprises a hydrophillic polymer.

90. (Original) The coating of claim 89 wherein the polymer in the second layer comprises polyvinylpyrrolidone.

91. (Original) The coating of claim 75 further comprising a third layer having a composition different from the first layer and the second layer.

92. (Original) The coating of claim 54 wherein the therapeutic agent is a member of the group consisting of, vasoactive agents, neuroactive agents, hormones, growth factors, cytokines, anaesthetics, steroids, anticoagulants, anti-inflammatories, immunomodulating agents, cytotoxic agents, antibiotics, antivirals, antibodies, anti-thrombogenic agents such as heparin, heparin

derivatives, urokinase, and PPack (dextrophenylalanine proline arginine chloromethylketone); anti-proliferative agents such as enoxaprin, angiopeptin, antibodies capable of blocking smooth muscle cell proliferation, hirudin, acetylsalicylic acid; anti-inflammatory agents, dexamethasone, prednisolone, corticosterone, budesonide, estrogen, sulfasalazine, and mesalamine, 5-fluorouracil, cisplatin, vinblastine, vincristine, epothilones, endostatin, angiostatin and thymidine kinase inhibitors; anesthetic agents such as lidocaine, bupivacaine, and ropivacaine; anti-coagulants, D-Phe-Pro-Arg chloromethyl ketone, an RGD peptide-containing compound, heparin, antithrombin compounds, platelet receptor antagonists, anti-thrombin, anti-platelet receptor antibodies, aspirin, prostaglandin inhibitors, platelet inhibitors, antiplatelet peptides, vascular cell growth promoters, growth factor inhibitors, growth factor receptor antagonists, transcriptional activators, translational promoters, vascular cell growth inhibitors, growth factor receptor antagonists, transcriptional repressors, translational repressors, replication inhibitors, inhibitory antibodies, antibodies directed against growth factors, cholesterol-lowering agents, vasodilating agents, agents which interfere with endogenous vasoactive mechanisms, a radiopharmaceutical, an analgesic drug, an anesthetic agent, an anorectic agent, an anti-anemia agent, an anti-asthma agent, an anti-diabetic agent, an antihistamine, an anti-inflammatory drug, an antibiotic drug, an antimuscarinic drug, an anti-neoplastic drug, an antiviral drug, a cardiovascular drug, a central nervous system stimulator, a central nervous system depressant, an anti-depressant, an anti-epileptic, an anxyolitic agent, a hypnotic agent, a sedative, an anti-psychotic drug, a beta blocker, a hemostatic agent, a hormone, a vasodilator, a vasoconstrictor, and a vitamin.

93. (Original) The coating of claim 54 wherein the therapeutic agent comprises paclitaxel.

94. (Original) The coating of claim 54 wherein the device is selected from the group consisting of an implantable device, a device used topically on a patient, a device that contacts a

living tissue, a catheter; a guide-wires, an embolizing coil; a vascular graft, a heart valve, an implantable cardiovascular defibrillator, a pacemaker, a surgical patch, a wound closure, a microsphere, a biosensors, an implantable sensor, an ex-vivo sensor, an ocular implant, a contact lens; and a tissue engineering scaffold.

95. (Original) The coating of claim 54 wherein the device comprises a stent.

96. (Original) The coating of claim 54 wherein the glass transition temperature of the first monomer unit is below about 37 degrees Centigrade and the glass transition temperature of the second monomer unit is above about 37 degrees Centigrade.

97. (Previously Presented) The coating of claim 54 wherein the copolymer is made from a combination of monomer units and has a glass transition temperature in a range of about 0 to about 60 degrees Celsius as measured using differential scanning calorimetery.

98. (Previously Presented) The coating of claim 54 wherein the copolymer is made from a combination of monomer units and has a glass transition temperature in a range of about 15 to about 40 degrees Celsius as measured using differential scanning calorimetery.

99. (Previously Presented) The coating of claim 54 wherein the copolymer is made from a combination of monomer units and has a glass transition temperature in a range of about -70 to about 70 degrees Celsius as measured using differential scanning calorimetery.

100. (Original) The coating of claim 99 wherein the combination comprises at least one monomer unit selected from the group consisting of butyl acrylate, butyl methylmethacrylate, and hydroxyethylmethacrylate.

101. (Original) The coating of claim 99 wherein the first monomer unit and the second monomer unit are selected from a member of the group consisting of acrylic acid, acrlonitrile, allyamine, acrylates, methacrylates, methylmethacrylate, alkyl acrylates, alkyl methacrylate, butadiene, carbomethylsilane, (carbonate) urethane, acrylates of polydimethyl siloxanes / methacrylates of polydimethyl siloxane ethylene, ethylene glycol, propylene glycol, (ether) urethane, urethane, vinyl chloride, vinyl alcohol, maleic anhydride, cellulose nitrate, carboxy methyl cellulose, dextran, dextran sulphate, propylene, esters, carbonates, ethers, butenes, maleic acid, fluoropolymer monomeric units, unsaturated polymer monomeric units, isoprene, melamine, sulphone, ureas, biological polymer monomeric units, protein, gelatin, collagen, elastin, butyl methacrylate, hydroxyethyl methacrylate, acrylic acid, methacrylate acid, polyethylene glycol dimethacrylate, polypropylene glycol diglycidal ether, polyethylene glycol diglycidyl ether, isocyanatoethyl methacrylate, N-acryloxysuccinimide, glycidyl methacrylate, hexamethylene diisocyanate, acrolein, crotonaldehyde, glycerol monomethacrylate, heparin methacrylate, methacryloyloxyethyl, methacryloylethyl phosphorylcholine polyacrylate, polyester, polyether, polyethylene glycol, butyl acrylate, polyethylene glycol monomethacrylate, isobutyl methacrylate, cyclohexyl methacrylate, ethyl acrylate, 2-hydroxyethyl acrylate, 2-ethylhexyl methacrylate, ethyl methacrylate, methyl acrylate, hexadecyl methacrylate, octadecyl methacrylate, styrene, methyl styrene, vinyl sterate, vinyl toluene, and tert-butyl acrylate.

102. (Original) The coating of claim 99 wherein the copolymer further comprises a third monomer unit, wherein the third monomer unit forms a homopolymer with a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of a homopolymer formed by the first monomer unit.

103. (Original) The coating of claim 99 wherein the first monomer unit comprises an acrylate, the second monomer unit compromises a methacrylate, and the third monomer unit comprises a methacrylate.

104. (Original) The coating of claim 99 wherein the copolymer comprises at least two methacrylate monomer units.

105. -150. (Cancelled)

151. (Previously Presented) An expandable medical device associated with a material composition for delivery of a therapeutic agent, comprising: an expandable portion of an expandable stent coated with a composition comprising the therapeutic agent associated with a copolymer free of covalent crosslinks that has a weight averaged molecular weight of at least about 2500, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit.

152. (Previously Presented) The device of claim 151 wherein at least a portion of the first monomer units are organized into a plurality of blocks consisting essentially of repeats of the first monomer unit, and at least a portion of the second monomer units are organized into a plurality of blocks consisting essentially of repeats of the second monomer unit.

153. (Previously Presented) The device of claim 152 wherein the copolymer further comprises regions of random copolymer bonding.

154. (Previously Presented) The device of claim 152 wherein the copolymer comprises acrylate blocks and methacrylate blocks.

155. (Previously Presented) The device of claim 151 wherein the copolymer comprises a third monomer unit and comprises at least three blocks, wherein each block consists essentially of repeats of one type of monomer unit.

156. (Previously Presented) The device of claim 151 wherein the therapeutic agent associates with blocks within the copolymer.

157. (Previously Presented) The device of claim 151, wherein the second monomer unit has a glass transition temperature that is at least about 70 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

158. (Previously Presented) The device of claim 151 wherein the monomer units are polymerizable to form the copolymer after the monomer units have been associated with the medical device.

159. (Previously Presented) The device of claim 151 wherein the therapeutic agent is paclitaxel.

160. (Previously Presented) The device of claim 151 wherein the copolymer is prepared and is subsequently associated with the therapeutic agent.

161. (Previously Presented) The device of claim 151 wherein the copolymer is prepared from the monomer units from a melt of the monomers.

162. (Previously Presented) The device of claim 151 wherein the first monomer unit and the second monomer unit are chosen so that the first monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the first monomer unit and the second monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the second monomer unit.

163. (Previously Presented) The device of claim 151 further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

164. (Previously Presented) The device of claim 163 wherein the second layer comprises a polymer that is covalently crosslinked to a polymer of the first layer.

165. (Previously Presented) The device of claim 164 wherein the polymer of the second layer comprises monomer units that comprise a heparin macromer.

166. (Previously Presented) The device of claim 163 wherein the polymer of the second layer comprises a second functional group that forms at least one of the covalent crosslinks in response to exposure to light.

167. (Previously Presented) The device of claim 151 wherein the copolymer glass transition temperature is between 26 and about 40 degrees Centigrade.

168. (Previously Presented) The device of claim 151 wherein the composition associated with the stent has a thickness ranging from about 0.1 μm to about 30 μm.

169. (Previously Presented) The coating of claim 54 wherein the thickness ranges from about 1 μm to about 200 μm.

170. (Previously Presented) A coating for a medical device for delivery of a therapeutic agent, the coating comprising a layer having a composition associated with at least a portion of the device, wherein the composition comprises the therapeutic agent associated with a copolymer that has a weight averaged molecular weight of at least about 2500 and a glass transition temperature between 26 and about 40 degrees Centigrade as measured by differential scanning calorimetery, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit, wherein the layer has a glass transition temperature between 26 and about 40 degrees Centigrade as measured by differential scanning calorimetery.

171. (Previously Presented) The coating of claim 170 wherein at least a portion of the first monomer units are organized into a plurality of blocks consisting essentially of repeats of the first monomer unit, and at least a portion of the second monomer units are organized into a plurality of blocks consisting essentially of repeats of the second monomer unit.

172. (Previously Presented) The coating of claim 170 wherein the copolymer further comprises regions of random copolymer bonding.

173. (Previously Presented) The coating of claim 170 wherein the copolymer comprises a third monomer unit and comprises at least three blocks, wherein each block consists essentially of repeats of one type of monomer unit.

174. (Previously Presented) The coating of claim 170 wherein the copolymer comprises acrylate blocks and methacrylate blocks.

175. (Previously Presented) The coating of claim 170 wherein the therapeutic agent associates with blocks within the copolymer.

176. (Previously Presented) The coating of claim 170, wherein the second monomer unit has a glass transition temperature that is at least about 70 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

177. (Previously Presented) The coating of claim 170 wherein the monomer units are polymerizable to form the copolymer after the monomer units have been associated with the medical device.

178. (Previously Presented) The coating of claim 170 wherein the medical device is a stent and the therapeutic agent is paclitaxel.

179. (Previously Presented) The coating of claim 170 wherein the copolymer is prepared and is subsequently associated with the therapeutic agent.

180. (Previously Presented) The coating of claim 170 wherein the copolymer is prepared from the monomer units from a melt of the monomers.

181. (Previously Presented) The coating of claim 170 wherein the first monomer unit and the second monomer unit are chosen so that the first monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the first monomer unit and the second monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the second monomer unit.

182. (Previously Presented) The coating of claim 170 further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

183. (Previously Presented) The coating of claim 182 wherein the second layer comprises a polymer that is covalently crosslinked to a polymer of the first layer.

184. (Previously Presented) The coating of claim 183 wherein the polymer of the second layer comprises monomer units that comprise a heparin macromer.

185. (Previously Presented) The coating of claim 183 wherein the polymer of the second layer comprises a second functional group that forms at least one of the covalent crosslinks in response to exposure to light.

186. (Previously Presented) The coating of claim 170 wherein the medical device is a stent, with the coating being applied to every expandable portion of the stent.

187. (Previously Presented) The coating of claim 170 wherein the medical device is a member of the group consisting of an implantable device, a device used topically on a patient, a device that contacts a living tissue, a catheter; a guide-wires, an embolizing coil, an implantable lead, an

expandable balloon, a vascular graft, a heart valve, an implantable cardiovascular defibrillator, a pacemaker, a surgical patch, a wound closure, a microsphere, a biosensors, an implantable sensor, an ex-vivo sensor, an ocular implant, a contact lens, and a tissue engineering scaffold.

188. (Previously Presented) The coating of claim 170 having a thickness of between about 0.1 μm and about 1000 μm.

189. (Previously Presented) The coating of claim 170 having a thickness of between about 1 μm and about 200 μm.

190. (Previously Presented) A coating for a medical device for delivery of a therapeutic agent, the coating comprising a layer having a composition associated with at least a portion of the device, wherein the composition comprises the therapeutic agent associated with a copolymer free of covalent crosslinks that has a weight averaged molecular weight of at least about 2500, wherein the copolymer comprises a first monomer unit and a second monomer unit, wherein the second monomer unit has a glass transition temperature that is at least about 30 degrees Centigrade higher than the glass transition temperature of the first monomer unit, with a glass transition temperature of a monomer unit being defined as a glass transition temperature of a homopolymer of that monomer unit, wherein the device is selected from the group consisting of an implantable device, a device used topically on a patient, a device that contacts a living tissue, a catheter; a guide-wires, an embolizing coil, an implantable lead, an expandable balloon, a vascular graft, a heart valve, an implantable cardiovascular defibrillator, a pacemaker, a surgical patch, a wound closure, a microsphere, a biosensors, an implantable sensor, an ex-vivo sensor, an ocular implant, a contact lens, and a tissue engineering scaffold.

191. (Previously Presented) The coating of claim 190 wherein at least a portion of the first monomer units are organized into a plurality of blocks consisting essentially of repeats of the first monomer unit, and at least a portion of the second monomer units are organized into a plurality of blocks consisting essentially of repeats of the second monomer unit.

192. (Previously Presented) The coating of claim 191 wherein the copolymer further comprises regions of random copolymer bonding.

193. (Previously Presented) The coating of claim 190 wherein the copolymer comprises a third monomer unit and comprises at least three blocks, wherein each block consists essentially of repeats of one type of monomer unit.

194. (Previously Presented) The coating of claim 190 wherein the copolymer comprises acrylate blocks and methacrylate blocks.

195. (Previously Presented) The coating of claim 190 wherein the therapeutic agent associates with blocks within the copolymer.

196. (Previously Presented) The coating of claim 190, wherein the second monomer unit has a glass transition temperature that is at least about 70 degrees Centigrade higher than the glass transition temperature of the first monomer unit.

197. (Previously Presented) The coating of claim 190 wherein the monomer units are polymerizable to form the copolymer after the monomer units have been associated with the medical device.

198. (Cancelled)

199. (Previously Presented) The coating of claim 190 wherein the copolymer is prepared and is subsequently associated with the therapeutic agent.

200. (Previously Presented) The coating of claim 190 wherein the copolymer is prepared from the monomer units from a melt of the monomers.

201. (Previously Presented) The coating of claim 190 wherein the first monomer unit and the second monomer unit are chosen so that the first monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the first monomer unit and the second monomer unit reacts to form a plurality of blocks consisting essentially of repeats of the second monomer unit.

202. (Previously Presented) The coating of claim 190 further comprising a second layer that contacts at least a portion of the first layer, wherein the second layer and the first layer have a different composition.

203. (Previously Presented) The coating of claim 202 wherein the second layer comprises a polymer that is covalently crosslinked to a polymer of the first layer.

204. (Previously Presented) The coating of claim 203 wherein the polymer of the second layer comprises monomer units that comprise a heparin macromer.

205. (Previously Presented) The coating of claim 203 wherein the polymer of the second layer comprises a second functional group that forms at least one of the covalent crosslinks in response to exposure to light.

206. (Previously Presented) The coating of claim 190 wherein the copolymer has a glass transition temperature between 26 and about 40 degrees Centigrade.

207. (Cancelled)

208. (Cancelled)

209. (Previously Presented) The coating of claim 190 having a thickness of between about 0.1 μm and about 1000 μm.

210. (Previously Presented) The coating of claim 95 wherein the coating is disposed essentially only on the solid portions of the stent.

211. (Previously Presented) The coating of claim 95 wherein the coating is disposed on both a lumen and exterior of the stent.

212. (Previously Presented) The coating of claim 151 wherein the coating is disposed essentially only on the solid portions of the stent.

213. (Previously Presented) The coating of claim 151 wherein the coating is disposed on both a lumen and exterior of the stent.

214. (Previously Presented) The copolymer of claim 167 wherein the copolymer glass transition temperature is about 37°C.

215. (Previously Presented) The coating of claim 170 wherein the layer glass transition temperature is about 37°C.

EVIDENCE APPENDIX

None.

RELATED PROCEEDINGS APPENDIX

None.